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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,002	10/22/2003	Laurie B. Gower	UF-304XC2	5666

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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02/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/691,002

Applicant(s)

GOWER ET AL.

Examiner

David M. Naff

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 8, 11, 13, 15, 19-24, 31, 32, 34 and 79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 8, 11, 13, 15, 19-24, 31, 32, 34 and 79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

An amendment of 10/30/07 amended claims 8 and 15, and canceled claims 6, 9, 12, 14, 16, 18, 27-29, 33, 35-58, 62-74, 77 and 78.

Claims examined on the merits are 1-3, 5, 8, 11, 13, 15, 19-24, 31, 32, 34 and 79, which are all claims in the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5, 8, 11, 13, 15, 24, 31 and 79 are rejected under 35 U.S.C. 102(a) as being anticipated by Olszta (Biomimetic Mineralization of Type-I Collagen) (R9 on 1449 of 5/12/04) or Olszta (Biomimetic Mineralization of Type-I Collagen) (R11 on 1449 of

5/12/04) or Olszta (Biomimetic Mineralization of Collagen for Nanostructured Composites (R27 on 1449 of 3/15/04)).

The claims are drawn to an organic/inorganic composite comprising and organic fluid-swellaable fibrous matrix comprising fibers and
5 interstitial spaces, and an inorganic mineral phase of amorphous or crystalline structure that coats and infiltrates each of the fibers, and is embedded in the interstitial spaces.

Olszta R9, R11 or R27 disclose mineralization of collagen by preparing a calcium chloride solution, addition of short chain acidic
10 polymers (poly-L-aspartic acid and polyacrylic acid), addition of a collagen substrate, and vapor diffusion of ammonium carbonate. For example, see the 5th page of R9 and R27, and pages 15 and 16 of R11.

The mineralization of collagen as disclosed by Olszta R9, R11 or R27 produces a composite that is the same as presently claimed. The
15 collagen of the R9, R11 or R27 has fibers and interstitial spaces as claimed, and the composite produced by Olszta R9, R11 or R27 inherently has an inorganic mineral phase of amorphous or crystalline structure that coats and infiltrates each of the fibers, and is embedded in the interstitial spaces. The calcium chloride solution,
20 acidic polymer and ammonium carbonate of Olszta R9, R11 or R27 form a mineral precursor of Olszta R9, R11 or R27. The features of dependent claims are inherently contained by the composite produced as disclosed by Olszta R9, R11 or R27.

Claim Rejections - 35 USC § 103

Claims 19-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Liu (6,300,315 B1).

The claims require the composite to contain a biologically active agent.

Liu discloses producing a mineralized collagen membrane by adding calcium and phosphate ions to a collagen slurry (col 2, line 53 to col 3, line 21) to form precipitated calcium phosphate. A drug may be incorporated in the membrane (col 3, lines 57-65). Drugs include antibiotics, bone morphogenetic proteins, bone growth factors, skin growth factors, antiscarring agents and/or mixtures.

It would have been obvious to incorporate a biologically active agent when preparing the composite of Olszta R9, R11 or R27 to obtain the function of the agent as suggested by Liu incorporating a drug that is a biologically active agent in a mineralized collagen membrane.

Claim Rejections - 35 USC § 103

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 19-21 and 23 above, and further in view of Rhee et al.

The claim requires the biologically agent to be pendantly attached to the matrix.

Rhee et al is described above.

When incorporating a biologically active agent as suggested by Liu as above, it would have been obvious to attach the biologically active agent pendantly to a reactive group formed on the collagen of Olszta R9, R11 or R27 as suggested by Rhee et al rather than
5 incorporating the agent in the collagen.

Claim Rejections - 35 USC § 103

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Connelly et al (6,995,013 B2).

Claim 32 requires the composite to comprise seeded cells..

10 Connelly et al disclose using collagen to form a cell-scaffold having five layers (col 13, lines 38-42) for producing tissue, and that bone structure contains osteons formed of lamellae (col 2, lines 24-37).

It would have been obvious to seed the collagen of Olszta R9, R11
15 or R27 with cells as suggested by Connelly et al to form tissue.

Claim Rejections - 35 USC § 103

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Song et al (5,418,222).

Claim 34 requires the matrix to comprise a film.

20 Song et al disclose a multiple layer collagen film having an adhesive between each layer for delivery of pharmaceuticals (col 5, lines 58-61).

It would have been obvious to provide the collagen of Olszta R9, R11 or R27 as a multiple layer film and adhere the layers together

with an adhesive as suggested by Song et al when desiring the function of a multiple layer film.

Response to Arguments

The amendment urges that Olszta R27 is material presented at a
5 Gordon Research Conference where there was a restriction that
information presented was not for public use as shown by Exhibit A
submitted with the amendment. However, this restriction would not
have appeared to prevent a member from using the information presented
for a non-public use such as in a laboratory where the information was
10 not disclosed as being derived from the conference, or would have
prevented a member from disclosing the invention to others when the
disclosure is private and not public. The restriction of the
conference does prevent the members from any use or disclosure of the
information obtained. When the information was presented at the
15 conference, it became known by others who could then disclose the
information to others in private.

The arguments concerning the 37 CFR § 1.132 Declaration by co-
inventor, Dr. Laurie B Grower, filed 12/26/06 is unpersuasive for the
type of reasons set forth in the previous office action. The concept
20 of the claimed invention is much broader than the specific process
described in Olszta R9 and R27, and the declaration fails to establish
that Dr. Douglas was also involved in conceiving the specific
procedures described by in Olszta R9 and R27. The declaration states
the Dr. Douglas was not directly involved in the experiments described

in Olszta R9 and R27. Conceiving a generic invention as claimed does not establish conceiving a specific species as described by in Olszta R9 and R27 within the scope of the generic invention.


The amendment urges that Exhibit B submitted with the amendment
5 lists Douglas and Gower as investigators. However, the present invention contains Olszta and Wheeler as co-inventors in addition to Douglas and Gower. Additionally, Exhibit B does not disclose the specific embodiments of Olszta R9 and R27. This is not an In re Katz situation since the present invention is by co-inventors who are not
10 authors.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be
15 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


David M. Naff
Primary Examiner
Art Unit 1657

DMN

15 2/4/08